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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,815	01/22/2004	Tette van der Lende	2183-6293US	4997

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/763,815

Applicant(s)

VAN DER LENDE, TETTE

Examiner

Casey Hagopian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20070321</u> |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/12/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Receipt is acknowledged of applicant's Request for Continuing Examination and IDS filed 3/12/2007. Claims 1-3 and 5-20 are currently pending.

MAINTAINED REJECTIONS

The following rejections are maintained:

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-3 and 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US 2002/0051844 A1) in view of Mahan, "Digestibility of soybean meals collected at four periods from a soybean processor (Cargill) in Ohio".

Wilson teaches animal food compositions and methods for increasing the reproductive performance of breeding populations of swine (abstract). Wilson also

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teaches incorporating any animal feed blend known in the art including rapeseed meal, cottonseed meal, soybean meal, and cornmeal as well as adding amino acids to the feed blend including arginine, lysine, methionine, threonine, tryptophan, and cysteine (paragraph 0031, Examples). Wilson also teaches several methods of administration ranging from feeding the composition to the animals daily for their lifetime, to feeding the composition to an animal before and/or during pregnancy and/or during lactation, and so on (paragraph 0030).

Wilson does not teach specific amounts of the amino acids.

Mahan teaches that soybean meal, a well-known feed material, naturally comprises amino acids including arginine, lysine, methionine, threonine, tryptophan, and cysteine and provides percentage amounts for each amino acid (Table 2). Mahan also teaches that soybean meal naturally contains 0.20% calcium (Table 2). One of ordinary skill in the art would have been motivated to optimize the particular amounts of amino acids in the composition taught by Wilson by way of routine experimentation. Absent of unexpected results, a practitioner would reasonably expect an animal feed composition to provide the same result as suggested by Wilson; to increase the reproductive performance of breeding populations of swine. Thus in Wilson, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the animal feed composition.

Response to Arguments

5. Applicant's arguments, see pages 6-9, filed 3/12/2007, with respect to the rejection of claims 1-3 and 5-20 under 35 USC 103 have been fully considered but they are not persuasive.

Applicant's main contentions are that Wilson is directed to the effect of ω -3 fatty acids and does not suggest the effect of arginine on the reproductive performance on swine. Applicant further argues that Wilson does not mention specific or relative amounts of amino acids in the animal feed. Applicant also argues that Mahan teaches a weight ratio between arginine and lysine to be lower than the claimed 1.5 and accordingly, there is no suggestion or motivation to modify or combine the references. Applicant further points to a report from the NRC as well as an Abstract from the ASAS. It is asserted that the NRC report states that "swine during pregnancy synthesize all the necessary arginine" and that "excessive supplements of arginine are undesirable as it can reduce feed intake and reduce growth" thereby one of ordinary skill in the art would not have reasonable expectation of success by increasing the arginine content of the feed. It is also asserted that the Abstract from the ASAS supports applicant's stance that the instant invention has unexpected results.

In response to applicant's arguments, the examiner respectfully points out that claims 1-10 and 20 are directed to a product and do not contain any limitation directed to the reproductive performance of swine. However assuming arguendo, any recitation of an intended use does not alone show patentable distinction. A recitation of intended use of the claimed invention must result in a structural difference between the claimed

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invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In other words, if the prior art structure is capable of performing the intended use, then it meets the claim. As for the method claims (claims 11-19), Wilson teaches a method for increasing the reproductive performance of breeding populations of swine comprising administering compositions that include animal feed blends such as rapeseed meal, cottonseed meal, soybean meal, and cornmeal (that contain amino acids naturally as evidenced by Mahan) and further optionally including additional amino acids (see 103 Rejection). Claim 11 currently reads, "A method for increasing the breeding productivity of an animal, said method comprising providing a diet to at least one gestating animal resulting in a daily dosage of 200-1300 mg arginine per kg body weight of said at least one gestating animal." It should be noted that the instant claims contain "comprising" open-ended language that allows for other method steps to be included. Wilson teaches the method as claimed, that is, increasing the breeding productivity of an animal by providing a diet to a gestating animal containing arginine. Wilson further exemplifies "breeding" formulations comprising soybean meal (SBM), which naturally contains arginine in the Examples section of the patent. While Wilson is silent to the relative or exact amounts of amino acids, Mahan teaches typical percentages of amino acids found in soybean meal. Specifically, Mahan teaches that soybean meal contains 3.56% arginine (which falls within the claimed range of instant claim 3), 2.97% lysine, 0.65% methionine, 0.76% cysteine, 0.61% tryptophan and 1.83% threonine. As applicant has pointed out, these percentages can be translated to ratios relative to the amount of lysine (i.e. arginine = 1.2, methionine + cysteine = 0.47,

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tryptophan = 0.21, and threonine = 0.61). While Mahan exhibits ratios for tryptophan and threonine within the claimed ratios, Mahan also exhibits ratios for arginine and methionine + cysteine that are less than the claimed ratios, as discussed above. However, Wilson teaches further adding amino acids to the feed blend that already contains the naturally occurring amino acids. Thus, Wilson teaches including additional amino acids to which is already naturally occurring in a typical feed such as soybean meal. Furthermore, it is within one skilled in the art to optimize a composition by altering formulations through routine experimentation. The MPEP clearly states that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentrations are critical (2144.05 (II)). It is also stated that the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine the optimum combination of percentages (see MPEP 2144.05 (II)). It should also be noted that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' composition differs and, if so, to what extent, from that of the prior art. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants. In regards to the NRC report and ASAS abstract, the examiner finds these arguments unpersuasive and irrelevant because the art relied upon in the 103 rejection does not discuss any harmful effects of arginine that would discourage one of ordinary skill in the art to add additional amounts of arginine to a feed blend and in fact, conversely teaches to add additional amino acids to feed blends that already naturally contain amino acids.

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For these reasons, the examiner respectfully disagrees with applicant's position and as such the rejection under 35 USC 103 is maintained.

Pertinent Art

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chalupa et al. (USPN 3,949,090) teaches animal feed compositions and methods thereof comprising well-known feed products including casein, soybean meal, and fish meal as well as amino acids including cysteine, methionine, lysine, threonine, arginine, and tryptophan and amounts thereof (columns 3-4).

Baba et al. (USPN 4,241,082) teaches animal feed compositions and methods thereof (i.e. promoting reproduction) comprising L-dopa and one or more amino acids, preferably L-arginine, as well as amounts and ratios thereof.

Conclusion

7. All claims have been rejected; no claims are allowed.

8. This is a continuation of the instant application. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

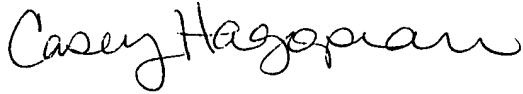
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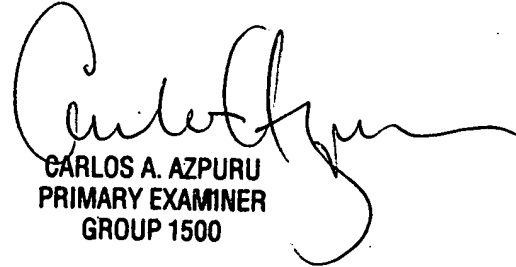
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Business Center (EBC) at 866-217-9197 (toll-free).



Casey Hagopian
Examiner
Art Unit 1615



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